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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/827,101	04/19/2004	Julius G. Hammerslag	HEMOSTA.022C1	1451
20995	7590	05/19/2005	EXAMINER	
KNOBBE MARTENS OLSON & BEAR LLP			RAMANA, ANURADHA	
2040 MAIN STREET			ART UNIT	
FOURTEENTH FLOOR			PAPER NUMBER	
IRVINE, CA 92614			3732	

DATE MAILED: 05/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/827,101

Applicant(s)

HAMMERSLAG, JULIUS G.

Examiner

Anu Ramana

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 March 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-29 and 31-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 19-24 is/are allowed.
- 6) ☒ Claim(s) 1,3-7,9-18,25-29 and 31-33 is/are rejected.
- 7) ☒ Claim(s) 8 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 5-7, 9-10, 12-15, 25-27 and 31-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Mandarin (US 3,030,951).

Mandarin discloses posterior and anterior spinal fusion by injecting a polyurethane polymer that polymerizes or “undergoes a chemical transformation” to cement the bony surfaces of adjacent vertebrae with preservation of cortical bone (Fig. 4, col. 1, lines 64-72, col. 2, lines 62-72 and col. 3, lines 8-24).

With regard to the limitation “minimally invasively joining the first bony surface and the second bony surface,” any surgical procedure is minimally invasive or “low trauma” to minimize damage to surrounding tissues.

The claimed method steps are inherently performed when a medium is injected between adjacent vertebrae as disclosed by Mandarin.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mandarin (US 3,030,951), as applied to claim 25.

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Although Mandarino does not disclose a specific treatment time, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have performed the operation within a range of 1 week to about one year, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mandarino (US 3,030,951), as applied to claim 12, in view of Anuta (Us 4,341,691).

Mandarino clearly discloses that the adhesive is injected, requiring a viscosity to aid flow of the material.

Mandarino does not disclose the viscosity of the adhesive.

Anuta teaches providing low viscosity (less than 1000 centipoise) to materials intended for injector use (Fig. 1, col. 1, lines 13-27 and col. 3, lines 23-28).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided the adhesive with a viscosity of no more than 100 centipoise, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Claims 1, 5-7, 9-10, 12-15, 25-27 and 31-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mandarino (US 3,030,951) in view of Foley et al. (US 5,902,231).

Mandarino discloses all elements of the claimed invention except for performing the procedure in a minimally invasive manner using a cannula or tubular introducer.

Foley et al. teach percutaneous minimally invasive surgery for all applications and procedures using a working channel such as a cannula (col. 1, lines 39-67, col. 2, lines 1-7 and col. 3, lines 10-15).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have performed vertebral joint repair utilizing an

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approach that is minimally invasive, as taught by Foley et al., to minimize damage to surrounding tissues.

Claims 4, 16 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mandarinino (US 3,030,951), as applied to claims 1, 12 and 25, in view of DiMatteo et al. (US 6,312,457).

Mandarinino discloses all elements of the claimed invention except for use of cyanoacrylate as an adhesive instead of polyurethane.

DiMatteo et al. teach the equivalence of polyurethane and cyanoacrylate as an adhesive material (col. 7, lines 15-18).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have utilized cyanoacrylates instead of polyurethanes for intervertebral stabilization, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended, herein adhesion, as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Claims 3, 11 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mandarinino (US 3,030,951), as applied to claims 1 and 12, in view of Preissmann (US 6,309,420).

Mandarinino discloses all elements of the claimed invention except for performing the procedure with radiographic visualization.

Preissman teaches the use of radiographic contrast agents in bone cements for viewing injection of bone cement or "medium" into a bone (col. 1, lines 56-69, col. 2, lines 36-37 and col. 4, lines 8-16).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have utilized fluoroscopic visualization, as taught by Preissman, in the method of fixing a vertebral joint disclosed by Mandarinino, to enable viewing of the path taken by the injected medium.

Response to Arguments

Applicant's arguments with respect to claims 1, 3-28 and 31-33 have been considered but are not persuasive. Applicant's arguments have been addressed in the rejections made in this office action.

The terminal disclaimer filed on February 14, 2005 has been approved. Accordingly, the double patenting rejections made in the office action mailed on December 15, 2004 have been withdrawn.

Allowable Subject Matter

Claim 8 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 19-20 are allowed.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anu Ramana whose telephone number is (571) 272-4718. The examiner can normally be reached Monday through Friday between 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Shaver can be reached at (571) 272-4720. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AR *Amuradillo Lamana*
May 14, 2005

Kevin Shaver
KEVIN SHAVER
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700